

REMARKS

Claims 35 and 64-68 are currently pending in this application. Claims 35, 66 and 68 have been amended. Support for the language “resorbable” in claims 35, 66 and 68 is found at least at page 1, line 26, of the specification. No new matter has been added. In view of the foregoing amendments and of the following remarks, Applicants submit that all pending claims 35 and 64-68 are in condition for allowance.

Claims 35 and 64-68 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 and 8 of U.S. Patent No. 6,638,531 (hereinafter “the ‘531 patent”) in view of Helmerhorst et al. (Applicants note that the Examiner discusses Haminishi et al., “A Self-Setting TTCP-DCPD Apatite Cement for Release of Vancomycin,” J. Biomed. Materials Res., 33:139-143, 1996, instead of Helmerhorst et al., in this rejection).

Applicants respectfully traverse this rejection and request that the rejection be reconsidered and withdrawn for the following reasons.

The claimed invention is directed to a bone material for the prevention and treatment of osteomyelitis, in which particular antimicrobial peptides (AMPs), namely SEQ ID NOs: 7, 8 and 9, have been incorporated in the bone material, wherein the antimicrobial peptides are released to the surrounding area for a period of time and wherein the bone material forms a resorbable bone cement after curing in which the antimicrobial peptides are distributed homogeneously in the cured resorbable bone cement.

Applicants respectfully submit that one skilled in the art would never be motivated to combine the pharmaceutical composition of antimicrobial peptides disclosed in the ‘531 patent with the bone cement disclosed by Haminishi et al. This is because, as disclosed in the ‘531 patent, at column 3, line 66 to column 4, line 8 (as well as being

generally understood by those skilled in the art), the pharmaceutical composition discussed therein solely is meant to administer antimicrobial peptides to a patient in need thereof to treat microbial infections. A skilled artisan never would use a bone cement as a vehicle for administering antibiotics to a patient requiring treatment for a microbial infection. It is, in fact, the reverse: bone cement comprising antimicrobial peptides is a specific means to prevent or inhibit bacterial infection at the time of surgical deposition of the bone cement in a patient's body for bone repair; bone cement is not used as a pharmaceutical composition for treating microbial infections, as disclosed in the '531 patent, as well as being generally understood by one skilled in the art. It is well known that problems of infection may arise when bone cement is deposited by surgery in the body. Thus, the claimed invention provides a bone cement having antimicrobial peptides incorporated therein to prevent or inhibit microbial infection in patients not suffering from an infection but rather needing bone repair, whereas the pharmaceutical composition of the '531 patent is administered to patients that are suffering with an infection.

Moreover, the claimed invention provides the unexpected and surprising finding that the antimicrobial peptides claimed therein, because to their unique nature, i.e. being of human origin, do not lead to resistant bacteria, which could occur if an antibiotic, such as vancomycin, as disclosed in Haminishi et al., is incorporated in a resorbable bone cement. Indeed, Haminishi et al. do not disclose or suggest the use of a resorbable bone cement, but merely disclose, in a strictly academic approach, a non-resorbable bone cement for studying the release of different compounds, such as vancomycin. Nowhere do Haminishi et al. disclose or suggest that their bone cement would be useful in practice. This lack of disclosure is not surprising because of the above-described risk of bacterial resistance that could occur within a patient's body upon implanting a bone cement incorporated with a

common antibiotic. The claimed invention, therefore, provides a surprising advantage of using antimicrobial peptides which do not risk creating antibiotic-resistant bacteria. The mere fact that Haminishi et al. teach the incorporation of vancomycin in a non-resorbable bone cement does not render the use of the unique antimicrobial peptides in a resorbable bone cement of the claimed invention obvious.

Applicants respectfully submit, therefore, that neither the '531 patent nor Haminishi et al. (or Helmerhorst et al.) teaches or suggests, either alone or in combination, the claimed invention, namely, providing antimicrobial peptides of human origin in resorbable bone cement, which, for the first time, provides a unique and suitable tool to prevent or inhibit microbial infections typically observed when bone cement is implanted, as well as avoiding the risk of creating antibiotic-resistant bacteria.

Claims 35 and 64-68 stand rejected under 35 U.S.C. § 102(f) for asserted lack of inventorship. Claims 35 and 64-68 stand rejected under 35 U.S.C. § 102(g) based upon claims 1-3 of the '531 patent.

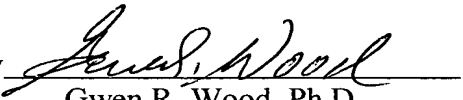
For the reasons provided above with respect to the provisional rejection under the judicially created doctrine of obviousness-type double patenting over claims 1 and 8 of the '531 patent in view of Helmerhorst et al. (and apparently Haminishi et al.), Applicants respectfully submit that claims 35 and 64-68 have been distinguished successfully from the teachings of the '531 patent in view of Helmerhorst et al. (and apparently Haminishi et al.), thus obviating this rejection.

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In view of the foregoing amendments and remarks, it is respectfully submitted that all pending claims 35 and 64-68 are distinguishable from the cited prior art. Accordingly, reconsideration and withdrawal of the rejection and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

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